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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/234,606 01/21/99 WOLFF

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EXAMINER

HM12/0215

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ART UNIT

PAPER NUMBER

1633

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/234,606

Applicant(s)
Wolff et al.

Examiner
Dave Nguyen

Group Art Unit
1633



☐ Responsive to communication(s) filed on _____

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 12 and 13 is/are allowed.

☒ Claim(s) 1-11 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Claims 1-13 are pending for examination.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 3-5 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility.

Specifically, claim 3 recites a process for delivering a compound to a cell, wherein a polymer complex comprising a chelator bound to a polymer comprising nucleic acids, proteins, genes, antisense polymers, DNA/RNA hybrids, and synthetic polymers. However, while no art is cited, the process as claimed requires that all of the listed components: unspecified nucleic acids, proteins, genes, antisense polymers, DNA/RNA hybrids, and synthetic polymers, are all employed together in the delivery process. The claimed process are not supported by either a specific asserted utility or a well established utility because the specification states that the claimed invention is useful for delivery of biological molecules to a cell, and neither the specification as filed nor any art of record discloses or suggests any property or activity of the complex as claimed. While there are well established utility for process of delivering nucleic acid molecules or protein molecules or ligand complexed with DNA molecules to a cell either for diagnostic purposes and/or therapeutic purposes at the time the invention was made either, the complex as recited in the claim is unspecified, and it is not apparent as to what is or are exactly the utilities of the delivery of a polymeric complex comprising unspecified nucleic acids, proteins, genes, antisense polymers, and DNA/RNA hybrids, for example, particularly on the basis of applicant's disclosure. Absent a disclosure of a specific asserted utility or a well established utility of the claimed process cited in claim 3, the asserted utility of general delivery of biological molecules to a cell lacks specificity. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112, second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly

- claiming the subject matter which the application regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and claims dependent therefrom are indefinite because claim 1 lacks a stated step that positively links to the preamble of the claim. The preamble of the claim 1 recites a process for the delivery of a compound to a cell; however, none of the recited steps of claim 1 recite the "compound". Thus, it is not apparent as to how the recited steps effect the delivery of the compound to the cell.

Claim 4 is indefinite in the recitation of "the chelator comprises a crown ether system". The specification on page 10 states that "a chelator is a polydentate ligand, a molecule that can occupy more than one site in the coordination sphere of an ion. The specification on page 13 also indicates that the "crown ether system" is constructed by mixing a chelator such as crown ether with a polymer backbone. Claim 4 is vague and confusing because it is not apparent how a chelator comprises a crown ether system,

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particularly since the specification states that the crown ether system is composed of a chelator bound to a polymer. The claim is also indefinite because it is not apparent whether or not the word "system" refers to a process step and/or a product.

Claim 3 is indefinite in the recitation of "wherein the first polymer and the second polymer comprise" because it is not apparent whether or not the recitation refers to the polymer wherein the first polymer and the second polymer, each of which comprises the recited elements, and/or wherein the first polymer and the second polymer each of which comprises some of the listed elements but both contains all of the listed elements. If the latter is the case, the recitation does not indicate as to what are exactly contained in the first polymer and in the second polymer.

Claim 5 is indefinite in the recitation of "the crown ether system comprises covalently binding the crown ether to the second polymer" because it is not apparent as to how the step of covalently binding the crown ether to the second polymer is contained physically in a product of a polymer. In addition, claim 5 is dependent from claim 2 which clearly recites that the "second polymer" is contained in the polymer of claim 1. In view of claim 2 from which claim 5 is dependent and in view of the definition of "the chelator" as indicated in the specification, it is not apparent how "the second polymer" is contained in the chelator as presently claimed in claim 5.

Claim 10 is indefinite because it is not apparent as to how the delivering step b) contributes to the "compacting a nucleic acid" as indicated in the preamble of the claim.

In claim 11, the term "the complex" lacks an antecedent basis. The claim is also indefinite because the claim refers to "the complex of claim 10"; however, claim 10 is clearly drawn to a process for compacting a nucleic acid. Thus, it is not apparent as to what are exactly meant by the term "the complex of claim 10".

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Hansen (US Pat No. 5,851,527).

The claims encompass a process for delivery of chemical drugs, and protein polymers coding for toxins or cytokines to a cell, which process comprises associating a chelator to a polymeric carrier that contains one or more polymers and an targeted antibody, and delivering the associated carrier to a cell, wherein the one or more polymers include polylysine and dextran polymers.

Hansen teach an identical delivery process as indicate above on column 11, lines 1-51, and column 13, first and second paragraphs.

Absent evidence to the contrary, the delivery process of Hansen has all of the properties cited in the claims.

Claims 1, 2, and 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Hnatowich *et al.* (US Pat No. 5,980,861).

The claims encompass a process for delivery of radiolabeled nucleic acid molecules or radiolabeled peptide nucleic acid to a cell, which process comprises associating a crown ether to either a nucleic acid polymer or a peptide nucleic acid polymer through a polyamine linker, mixing the crown ether containing nucleic acid polymer with a polymer carrier, and delivering the crown ether containing nucleic acid polymer complexed with the polymeric polymer to a cell.

Hnatowich *et al.* teach an identical delivery process as indicated above on column 2 bridging column 3; column 3 bridging column 4; column 6, last paragraph; column 9, first paragraph; column 11,

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lines 1 to lines 54; column 12 bridging column 13; column 19, first paragraph; and columns 43 and 44.

Absent evidence to the contrary, the delivery process cited in Hnatowich *et al.* has all of the properties cited in the claims.

Claim 10-13 are free of the art of record because the art of record does not teach or suggest a complex comprising a nucleic acid molecule, a polymer associated with a plurality of chelators by ionic or covalent bonding and methods using the complex to compact the nucleic acid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Dave Nguyen* whose telephone number is (703) 305-2024.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John Leguyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Dave Nguyen

Patent Examiner

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